REMARKS

Reconsideration of the rejections based upon the foregoing amendments and the following remarks is respectfully requested.

A. Allowable Subject Matter

Applicants would like to thank the Examiner for indicating that claims 41-59 contain allowable subject matter.

B. Claims 1, 5, and 9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) in view of pages 320-322 of Microsystem Design by Stephen Senturia, Kluwer Academic Publishers (2002) ("Microsystem Design").

The Office Action concedes that the Neel reference does not disclose "whether the response indicates that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat" (OA page 4). The Office Action attempts to cure this deficiency in Neel by citing Microsystem Design for the proposition that "it was known at the time of the invention that the profiles of the fluid flow fronts in microchannels can have different shapes, such as concave or convex, depending on the fluid, chemistry of the capillary surface, contamination, and surface roughness" (OA pages 4-5). It is respectfully submitted that the disclosure of Microsystem Design does not support this assertion.

Microsystem Design only pertains to vertical capillaries

The disclosure of Microsystem Design is only relevant to vertical cylindrical capillary channels, as it details the interaction between the upward capillary force in the vertical cylindrical capillary tube and the downward force of gravity. Therefore, the disclosure of Microsystem Design is not relevant to the flow front in a biosensor that can be in any orientation with respect to the ground, as the direction in which the force of gravity will operate on the fluid column can not be predicted in advance and is subject to change with great likelihood during the capillary filling portion of the test.

Microsystem Design only pertains to static fluid fronts

The disclosure of Microsystem Design only deals with the shape of the static fluid front in such channels ("The simplest example is the static (equilibrium) rise of the liquid in the capillary," Microsystem Design, page 321, line 4). The claimed invention is directed toward dealing with a moving fluid front during a capillary filling operation. The disclosure of Microsystem Design does not provide any data as to the shape of the moving fluid front during the capillary filling process and is therefore inapplicable to the claimed invention.

Microsystem Design only pertains to vertical capillaries immersed in external pools of liquid

Finally, the Microsystem Design disclosure is only relevant to capillary flow in a vertical channel placed in a pool of liquid extending outside the capillary channel. The disclosure of Microsystem Design could not be used by a biosensor designer to determine what shape the sample flow front would have in a particular biosensor because the equations given for calculating the contact angle θ (equations 13.9 and 13.10) require data on the height (h) of the

vertical column above the liquid surface outside the capillary, which would not be a consistent measurement for biosensor users placing the capillary opening at the site of blood drops of varying size.

Therefore, the disclosure of Microsystem Design is not relevant to the moving flow front that can be in any orientation with respect to the ground, and which does not flow from a pool of liquid of known dimensions maintained outside of the capillary.

Claims 1 and 5 are method claims

Perhaps most importantly, the Office Action ignores the fact that claims 1 and 5 are method claims. Claims 1 and 5 specifically require the step of "determining the presence or absence of a response to the test signal above a predetermined threshold, the response indicating that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat." The combination of Neel and Microsystem Design does not teach or suggest the above-recited element of Applicants' claims 1 and 5. Even assuming *arguendo* that Microsystem Design teaches that the flow fronts in a biosensor can be non-uniform (which it does not), this does not teach or suggest that the magnitude or shape of such non-uniformity is anything to be concerned about by the biosensor designer. Because the combination of references does not recognize that a non-uniform flow front in a biosensor capillary channel can be of a magnitude significant enough to give a false indication of dose sufficiency when the dose sufficiency electrodes are shorted by the conductive sample, the combination does not render Applicants' claims 1 and 5 obvious. Only the present Applicants have performed the tests, as detailed in the present specification, to recognize that this problem exists. Consequently, only the present Applicants have designed a biosensor system and method

that allows "indicating that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat" as required by claims 1 and 5. It is therefore respectfully submitted that claims 1 and 5 are allowable over the references of record.

Claim 9 depends from claim 5 and therefore includes all of the limitations of claim 5. It is therefore respectfully submitted that claim 9 is allowable for the same reasons set forth above with respect to claim 5.

C. Claims 2-4 and 6-8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) in view of pages 320-322 of Microsystem Design by Stephen Senturia, Kluwer Academic Publishers (2002) ("Microsystem Design"), and further in view of Beaty et al. (WO 99/32881 A1) ("Beaty") and Bedell ("Admittance and Impedance Loci," Proc. Phys. Soc. London 14 327-336(("Bedell").

Claims 2-4 depend from claim 1 and therefore include all of the limitations of claim 1. Claims 6-8 depend from claim 5 and therefore include all of the limitations of claim 5. The arguments set forth above in Section B with respect to the Neel and Microsystem Design references are therefore also applicable to claims 2-4 and 6-8. Claims 2 and 6 add the limitation "wherein the test signal is an AC signal," claims 3 and 7 add the limitation "wherein the response comprises magnitude and phase angle information", and claims 4 and 8 add the limitation "wherein the response comprises an admittance value". The combination of set forth in the Office Action does not teach or suggest these limitations of Applicants' claims 2-4 and 6-8.

The Office Action concedes that Neel teaches the use of a DC signal applied to dose sufficiency electrodes, but does not disclose the use of a signal having an AC component. In an attempt to cure this deficiency, the Office Action suggests that Beaty discloses applying an AC

test signal to measurement electrodes to determine sample volume sufficiency, therefore it would have been obvious to use an AC signal with the dose sufficiency electrodes of Neel.

It is respectfully submitted that, rather than rendering the claimed invention obvious, the combination of Neel and Beaty teach away from the present invention. Neel teaches the use of a separate pair of dose sufficiency electrodes and the application of a DC signal thereto. The reason that Neel uses a separate pair of dose sufficiency electrodes (i.e. separate from the measurement electrodes) is that Neel does not want to apply the DC signal to the measurement electrodes and thereby disturb the reaction between the sample and the reagent in the measurement zone. By applying the DC signal to the dose sufficiency electrodes and leaving an open circuit between the measurement electrodes, the stoichiometry of the measurement zone is not disturbed until the measurement sequence is ready to begin. See Neel, col. 14, line 55 to col. 15, line 25.

Beaty, on the other hand, teaches that the adequacy of the sample volume can be determined by applying an AC signal of proper level directly to the measurement electrodes, without the need for separate dose sufficiency electrodes. This is because the AC signal will not drive the sample redox reaction in one direction. Therefore, a combination of Neel and Beaty teaches that the separate dose sufficiency electrodes of Neel are unnecessary since the application of an AC signal to the measurement electrodes achieves the same result without the need for an additional pair of dose sufficiency electrodes. There is nothing in the combination that would suggest to one of ordinary skill in the art that the AC signal should be applied to separate dose sufficiency electrodes. It is therefore respectfully submitted that Applicants' claims 2-4 and 6-8 are allowable in view of the cited references.

D. Claims 10, 11, 14-17, 20-22, 25-29, 32, 33 and 36-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) in view of Beaty et al. (WO 99/32881 A1) ("Beaty"). Claims 12, 13, 18, 19, 23, 24, 30, 31, 34, 35, 39 and 40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) in view of Beaty et al. (WO 99/32881 A1) ("Beaty") and further in view of Bedell ("Admittance and Impedance Loci," Proc. Phys. Soc. London 14 327-336(("Bedell").

Applicant's claims 10 and 20 specifically require "applying a dose sufficiency test signal having an AC component to at least one of the dose sufficiency electrodes." Similarly, Applicants' claims 16, 27, 32 and 37 specifically require "applying a test signal having an AC component to one of the dose sufficiency electrodes." The combination of Neel and Beaty does not teach or suggest these limitations of Applicants' claims 10, 16, 20, 27, 32 and 37. The Office Action concedes that Neel teaches the use of a DC signal applied to dose sufficiency electrodes, but does not disclose the use of a signal having an AC component. In an attempt to cure this deficiency, the Office Action suggests that Beaty discloses applying an AC test signal to measurement electrodes to determine sample volume sufficiency, therefore it would have been obvious to use an AC signal with the dose sufficiency electrodes of Neel.

It is respectfully submitted that, rather than rendering the claimed invention obvious, the combination of Neel and Beaty teach away from the present invention. Neel teaches the use of a separate pair of dose sufficiency electrodes and the application of a DC signal thereto. The reason that Neel uses a separate pair of dose sufficiency electrodes (i.e. separate from the measurement electrodes) is that Neel does not want to apply the DC signal to the measurement electrodes and thereby disturb the reaction between the sample and the reagent in the measurement zone. By applying the DC signal to the dose sufficiency electrodes and leaving an open circuit between the measurement electrodes, the stoichiometry of the measurement zone is

not disturbed until the measurement sequence is ready to begin. See Neel, col. 14, line 55 to col. 15, line 25.

Beaty, on the other hand, teaches that the adequacy of the sample volume can be determined by applying an AC signal of proper level directly to the measurement electrodes, without the need for separate dose sufficiency electrodes. This is because the AC signal will not drive the sample redox reaction in one direction. Therefore, a combination of Neel and Beaty teaches that the separate dose sufficiency electrodes of Neel are unnecessary since the application of an AC signal to the measurement electrodes achieves the same result without the need for an additional pair of dose sufficiency electrodes. There is nothing in the combination that would suggest to one of ordinary skill in the art that the AC signal should be applied to separate dose sufficiency electrodes. It is therefore respectfully submitted that Applicants' claims 10, 16, 20, 27, 32 and 37 are allowable in view of the cited references.

Claims 11-15 depend from claim 10, claims 17-19 depend from claim 16, claims 21-26 depend from claim 20, claims 28-31 depend from claim 27, claims 33-36 depend from claim 32, and claims 38-40 depend from claim 37 and each of these dependent claims therefore include all of the limitations of the independent claims from which they depend. It is therefore respectfully submitted that claims 11-15, 17-19, 21-26, 28-31, 33-36 and 38-40 are allowable for the same reasons set forth above with respect to claims 10, 16, 20, 27, 32 and 37.

E. Claims 60-65 were rejected under 35 U.S.C. §103(a) as being unpatentable over Neel et al. (US 6,743,635 B2)

Applicants' claim 60 specifically requires "wherein the dose sufficiency electrodes have first edges substantially parallel to the length of the capillary chamber and second edges substantially perpendicular to the length of the capillary fill chamber with the first edges being of

greater length than the second edges." Applicants' claim 61 specifically requires "wherein the dose sufficiency electrodes have a first axis substantially parallel to the length of the capillary chamber and a second axis substantially perpendicular to the length of the capillary fill chamber with the first axis being of greater length than the second axis." Applicants' claim 62 specifically requires "wherein the dose sufficiency electrodes have first edges substantially parallel to the length of the fluid flow path and second edges substantially perpendicular to the length of the fluid flow path with the first edges being of greater length than the second edges." Applicants' claim 64 specifically requires "wherein the dose sufficiency electrodes have a first axis substantially parallel to the length of the fluid flow path and a second axis substantially perpendicular to the length of the fluid flow path with the first axis being of greater length than the second axis." The Office Action alleges that "[b]arring a contrary showing, such as unexpected results, having the length of the first edges be greater than the length of the second edges is just a consequence of optimizing the widths of different portions of the capillary fill chamber so that the sample adequately and quickly fills the capillary fill chamber." It is respectfully submitted that Applicants' disclosure has demonstrated such unexpected results. As disclosed on pages 57 and 58 of the present disclosure:

> An advantage of the parallel dose sufficiency electrode design of FIGs. 35 and 36, when used with AC excitation, is that there is substantially no electrical communication between the electrodes until the sample covers at least a portion of the edges along the electrode gap. Therefore, a sample exhibiting the concave flow front of FIG. 35A, where the illustrated sample is touching both of the dose sufficiency electrodes 3508,3510 but is not touching the electrode edges along the gap, will not produce any significant electrical communication between the dose sufficiency electrodes. The test meter will therefore not form a conclusion of dose sufficiency until the sample has actually bridged the dose sufficiency electrodes between the electrode edges along the gap. This will happen only after the rear-most portion of the concave flow front has reached the dose sufficiency electrodes 3508,3510, at which point the sample has completely covered the

measurement zone over the measurement electrodes. As can be seen in FIG. 35B, convex sample flow fronts will activate the dose sufficiency electrodes 3508,3510 as soon as the flow front reaches the dose sufficiency electrodes (at which point the sample has completely covered the measurement zone over the measurement electrodes).

Another advantage to the parallel dose sufficiency electrodes illustrated in FIGs. 35 and 36 is that the amount of signal transmitted between the electrodes is proportional to the amount of the gap edges that is covered by the sample. By employing an appropriate threshold value in the test meter, a conclusion of dose sufficiency can therefore be withheld until the sample has covered a predetermined portion of the dose sufficiency electrode gap edge. Furthermore, an analysis of the dose sufficiency signal will allow the test meter to record the percentage of fill of the capillary fill space for each measurement made by the test meter, if desired.

As can be seen, making the length of the first edges be of a greater length than the second edges allows the dose sufficiency electrodes to respond appropriately to a concave sample flow front, withholding an indication of sample sufficiency until the rear-most portion of the flow front reaches the gap between the electrodes. This arrangement also allows the utilization of the resulting signal that changes in proportion to the amount of the electrodes that are covered with sample, allowing a determination of how far into the capillary channel the sample has reached, and even the ability to measure the speed at which the capillary fill is progressing. It is therefore respectfully submitted that such unexpected results indicate that the claimed configuration is not a mere design choice, but rather an unexpected performance increase over prior art designs such as Neel's when the electrodes are configured as claimed. It is therefore respectfully submitted that claims 60-62 and 64 are allowable over the references of record.

Claim 63 depends from claim 62 and therefore includes all of the limitations of claim 62. It is therefore respectfully submitted that claim 63 is allowable for the same reasons set forth above with respect to claim 62.

Claim 65 depends from claim 64 and therefore includes all of the limitations of claim 64. It is therefore respectfully submitted that claim 65 is allowable for the same reasons set forth above with respect to claim 64.

F. Claims 51, 52, 57 and 58 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, it was noted by the Examiner that the phrase "the response" in each of these claims is ambiguous since claims 49 and 54 make reference to both a "first response" and a "second response." It is respectfully submitted that claims 51, 52, 57 and 58 have been amended herein in order to remove the indefiniteness noted by the Examiner. It is therefore respectfully submitted that claims 51, 52, 57 and 58 are allowable under 35 U.S.C. §112, second paragraph.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and respectfully request such action. Applicants respectfully request that the Examiner telephone the undersigned attorney for Applicants at 317-634-3456 if the Examiner does not find that all claims are in condition for allowance as presented herein.

Respectfully submitted,

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